

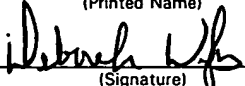


DAC

Atty. Dkt. No. 073406-0402

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Jerry Pelletier, et al.  
Title: DNA SEQUENCES FROM  
BACTERIOPHAGE 77 THAT  
ENCODE ANTI-MICROBIAL  
POLYPEPTIDES  
Appl. No.: 09/407,804  
Filing Date: 9/28/99  
Examiner: R. Mitra  
Art Unit: 1653

CERTIFICATE OF MAILING	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231, on the date below.	
Deborah Wykes	
(Printed Name)	
	
(Signature)	
December 16, 2002	
(Date of Deposit)	

TRANSMITTAL FOR PETITION TO THE COMMISSIONER

UNDER 37 CFR 1.181 OR 1.182

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Enclosed herewith are:

[ X ] Petition to the Commissioner under 37 CFR 1.181 or 1.182

[ X ] Postcard

Respectfully submitted,

Date 16 December 2002

By Wesley B Ames

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OFFICE OF PETITIONS



# 27

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**PETITION TO THE COMMISSIONER UNDER 37 CFR 1.181 OR 1.182**

Box DAC  
Commissioner for Patents  
Washington, D.C. 20231

Sir:

Applicant hereby renews its petition that up to 10 nucleotide sequences be allowed in the present application, reversing the decision of the Group Director. Thus, Applicant petitions the Commissioner to compel the Group Director of Technology Center 1600 to comply with the Notice provided in 1192 O.G. 68 allowing up to 10 independent nucleotide sequences to be claimed in one application. As appropriate, this petition may be considered as a petition under 37 CFR 1.181 to review a decision of a Technology Center Director (MPEP 1002.02(b)(15), a petition under 37 CFR 1.181 to invoke the supervisory authority of the Commissioner in a matter not otherwise provided for (MPEP 1002.02(b)(3), or a petition under 37 CFR 1.182 in a matter not otherwise provided for. In accordance with MPEP 1002.02(b) this petition is to be decided by the Office of the Deputy Commissioner for Patent Examination Policy.

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**OFFICE OF PETITIONS**

### Procedural Background

In Paper No. 15, mailed 4 August 2001, the examiner set forth a restriction requirement that required election of either claims directed to nucleic acid sequences and related claims (invention I), or claims directed to polypeptides (invention II), and that included the requirement to elect a single sequence. In response, Applicant elected the nucleic acid sequence claims (claim group I), and traversed the requirement that a single sequence be elected. In Paper No. 19, the examiner refused the inclusion of more than one nucleic acid sequence, and made the Restriction Requirement final.

On 8 July 2002, Applicant submitted a Petition under 37 CFR § 1.181 to compel the Group Director to adhere to the notice provided in 1192 O.G. 68 to allow up to 10 sequences in a single application. The Petition was dismissed as being premature, and was returned for consideration by the Group Director as a Petition under 37 CFR § 1.144. In the Decision on Petition dated October 15, 2002, the Group Director refused the Petition, asserting that the decision was consistent with 1192 O.G. 68 and MPEP 803.04. As indicated above, Applicant renews the Petition and requests that the Petition be considered by the Office of the Deputy Commissioner for Patent Examination Policy.

### Argument

The pending claims in the above-captioned application specify 6 nucleic acid sequences, with each sequence corresponding to a different open reading frame from Bacteriophage 77 (*Staphylococcus aureus* host). As described above, the Examiner in this case required the election of only one sequence for prosecution. Applicant objected to the restriction to one sequence, and requested that the Examiner comply with the Commissioner's Notice in 1192 O.G. 68 and with the examination guidelines for examiners provided in MPEP 803.04.

The Commissioner's Notice published as 1192 O.G. 68 states that:

[T]o further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided sua sponte to partially waive the requirement of 37 CFR 1.141 and permit

a reasonable number of such nucleotide sequences to be claimed in a single application.

Accordingly, in most cases, up to ten (10) independent and distinct nucleotide sequences will be examined in a single application without restriction.

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In some exceptional cases, the complex nature of the claimed material, for example a protein amino acid sequence reciting three dimensional folds, may necessitate that the reasonable number of sequences to be selected be less than ten (10).

In a telephonic interview with SPE Christopher Low, Applicant further discussed the restriction to one sequence. SPE Low confirmed that the examiners had been instructed to permit prosecution of only one sequence in an application, despite the instructions provided in 1192 OG 68 and MPEP 803.04. In a separate inquiry, it was confirmed that the instruction for the examiners to restrict applications to only one sequence was given by Technology Center 1600 Director John Doll.

In objecting to the Examiner's restriction to a single sequence, Applicant pointed out that the present case is in no way exceptional in the sense mentioned in 1192 O.G. 68. In response to this argument, the Examiner merely reiterated the observation that the 6 specified sequences encoded different polypeptides. However, this is precisely the type of situation for which the Notice indicates that up to 10 sequences will be permitted. As shown in the portion of the Notice quoted above, it is intended to normally allow up to 10 independent sequences, *i.e.*, sequences that encode different polypeptides, to be prosecuted in a single application, without restriction.

During the telephonic discussion referenced above, SPE Low stated that the Group had instituted the "one sequence" policy in order to reduce the time needed for sequence searching. However, this is irrelevant. Instead, the issue is whether examiners in Technology Center 1600 will or will not follow valid, current notices from the Commissioner.

With the current instructions to examiners in Technology Center 1600 to restrict applications to only one sequence, Technology Center 1600 has usurped the Commissioner's authority, and directly contravened 1192 O.G. 68. Further, the restriction to one sequence is directly contrary to the policy of encouraging biotechnology in the United States as stated in 1192 O.G. 68. To the contrary, the restriction to only one sequence acts as a blockade to the ability of

small biotech companies and individuals to obtain useful patent protection on inventions for which the claims specify nucleic acid sequences. Indeed, the policy of encouraging development of biotechnology is particularly important in the current environment of reduced investment. Therefore, maintenance of the policy and practice of allowing up to 10 independent sequences, as embodied in 1192 O.G. 68, is very important to development of the biotechnology industry.

Failure to reverse the unauthorized practice of Technology Center 1600 in restricting applications to only a single sequence will simply prevent biotech companies from obtaining patent protection on many otherwise patentable inventions, thereby significantly impairing biotechnology development.

The examiner's reasoning was effectively repeated in the Director's Decision on Petition mailed 15 October 2002. Despite the language and clear intent of 1192 O.G. 68, in the Decision on Petition the Director of Technology Center 1600 asserted that the limitation to only a single sequence in the present application is consistent with 1192 O.G. 68. The Directed attempted to justify this assertion by stating that the "Official Gazette Notice and MPEP 803.04 do not require examination of ten polynucleotide sequences in one application" and further asserted that "A restriction of one sequence is consistent with both the requirements of the OG Notice, MPEP 803.04 and 35 U.S.C. 121." The Director continued by stating that "one sequence falls within the range of 'up to ten' permitted by the Official Gazette Notice."

Applicant respectfully submits that the Director's interpretation of 1192 O.G. 68 is unreasonable, and attempts to make the exception applicable only to "exceptional cases" into the general rule. Adopting the Director's interpretation thus has the obvious effect of effectively eliminating 1192 O.G. 68. It is broadly recognized that interpretations that effectively eliminate a rule are only applied where no other interpretation is allowable.

In addition, contrary to the Director's assertion, 1192 O.G. 68 states that "in most cases, up to ten (10) independent and distinct nucleotide sequences will be examined in a single application without restriction." (Emphasis added.) Thus, the Notice contains a positive directive for the handling of "most cases", not an option for the examiner. According to the Notice, it is only for "some exceptional cases" where "the complex nature of the claimed material ... may necessitate that the reasonable number of sequences to be selected be less than ten (10)." Neither

the examiner nor the Director has even attempted to assert that the present claimed subject matter is exceptional due to its complex nature.

Once again, because the present claims do not concern material of a complex nature, these claims cannot fall within the limited exception allowed in 1192 O.G. 68. To the contrary, the present claims fall squarely within the normal rule for "most cases", so that up to 10 nucleic acid sequences are properly allowed without restriction.

In view of the facts and discussion above, Applicant respectfully requests that the instructions to the examiners in Technology Center 1600 and the present requirement restricting examination to a single sequence be reversed, and that Applicant be allowed to prosecute up to 10 independent sequences in this application in accordance with 1192 O.G. 68 and MPEP 803.04.

No fee is believed due in connection with this petition. However, if any fee is due, kindly charge Deposit Account 50-0872 for the appropriate amount.

Respectfully submitted,

Date 16 December 2002

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